



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/597,015

07/06/2006

John Colyer

9052-246

4772

20792 7590 12/23/2008
MYERS BIGEL SIBLEY & SAJOVEC
PO BOX 37428
RALEIGH, NC 27627

EXAMINER

CHEU, CHANGHWA J

ART UNIT

PAPER NUMBER

1641

MAIL DATE

DELIVERY MODE

12/23/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/597,015	Applicant(s) COLYER, JOHN	
	Examiner JACOB CHEU	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 September 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,28,30-52,54,56 and 57 is/are pending in the application.
- 4a) Of the above claim(s) 28,31-52,54 and 56 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,30 and 57 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/31/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I, claims 1, 30 and 57, in the reply filed on 9/17/2008 is acknowledged. Claims 2-27, 29, 53 and 55 are cancelled. Claims 28, 31-52, 54 and 56 are withdrawn from further consideration.
2. Applicant argues that the cited Blau et al. differs from the instant invention because Blau et al. reporter system uses an active reporter subunit which requires interaction with a second reporter subunit to perform the function, whereas the instant invention using scaffold material and a target moiety. The scaffold material is distinct and does not require any additional scaffold material to be active. Moreover, Blau et al. reporter system needs to fuse to a suitable reporter subunit, and the instant invention does not require such fusion.

Applicant's arguments have been considered, but are not persuasive.

Based on the recited language, the transitional wording uses "comprising" which means an open language. The recited language "comprising" does not preclude the scaffold material to fuse with another component. In addition, the instant recited language does not distinguish the mechanism from the Blau et al. teachings, e.g. requiring another additional component for proper function. Thus, the instant invention does not contribute to novelty or inventive step under PCT Rule 13.1.

Thus, the restriction is deemed proper and is FINAL.

Art Unit: 1641

Currently, claims 1, 30 and 57 are under examination.

Use Claim

3. Claim 1 provides for the use of the non-natural presentation system, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 1 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1, and 57 are rejected under 35 U.S.C. 102(b) as being anticipated by Blau et al. (WO 98/44350).

Art Unit: 1641

Blau et al. teach a reporter system component comprises a first low-affinity reporter subunit, coupled (covalently) to a first binding moiety, wherein the first low-affinity reporter subunit is capable of association with a second low-affinity reporter subunit to generate a detectable signal (See claim 1 and page 18, line 17-20).

6. Claims 1, 57 are rejected under 35 U.S.C. 102(e) as being anticipated by Leyland-Jones et al.(US 20030091975).

Leyland-Jones teaches a presentation system, i.e. test strip. The test strip comprises a contact zone where Leyland-Jones teaches covalently coupled the analyte (target moiety) with an antibody (scaffold material) capable of binding to the analyte (See section 0681). The complex, e.g. analyte (target moiety) can be recognized by a second antibody in the detection zone (See section 0683). Note, the domain of the first antibody is non-reactive for the binding of the second antibody since the second antibody is specific for the analyte (See Section 0683).

7. Claims 1 and 57 are rejected under 35 U.S.C. 102(b) as being anticipated by Abbott et al. (US 4521521).

Abbott et al. teach method of detecting analyte in a sample. Abbott et al. teach a “analyte-carrier conjugate” where the analyte is covalently attached to a protein. This fulfills the structure of the instant invention, i.e. target moiety (analyte) covalently bound to a scaffold material (protein) where the scaffold material is non-reactive to the binding of the partner to the analyte (Col. 4, line 60 to Col. 5, line 25).

Art Unit: 1641

8. Claims 1 and 57 are rejected under 35 U.S.C. 102(e) as being anticipated by Upmeier et al. (US 20040137425).

Upmeier et al. teach a method of detecting an analyte in a sample. Upmeier et al. teach covalently binding the analyte to a scaffold material, e.g. protein where the analyte can be recognized by a binding partner and the scaffold material is non-reactive to the binding of the binding partner to the analyte (See claim 1).

9. Claims 1 and 57 are rejected under 35 U.S.C. 102(b) as being anticipated by Ideker et al. (US 20020107640).

Ideker et al. teach a method of detecting an analyte in a sample. Ideker et al. teach covalently binding the analyte to a scaffold material, e.g. green fluorescent protein Cy3 or Cy5 where the analyte can be recognized by a binding partner and the scaffold material is non-reactive to the binding of the binding partner to the analyte (See Section 0070).

10. Claims 1 and 57 are rejected under 35 U.S.C. 102(b) as being anticipated by Caras et al. (US 5798448).

Caras et al. teach covalently binding of CD4-IgG (target moiety) with scaffold materials (protein A) in an immunoaffinity column (See Example 5).

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

13. Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Blau, in view of Zuk et al. (US 420847).

With respect to “kit”, Blau, Ideker, Upmeier, Caras, Abbot, and Leyland-Jones et al. do not explicitly teach a kit comprising the elements recited in claim 57. Zuk et al. teach that in performing assays, it is convenient and to combine the necessary reagents together in a kit (column 22, lines 20-35). Zuk et al. further teach that this may improve assay accuracy.

Therefore, it would have been prima facie obvious to one of ordinary skill in the art to have motivated Blau, Ideker, Upmeier, Abbot, Caras or Leyland-Jones et al. to place the covalently bound target-moiety with the scaffold material together as a kit for convenience and accuracy as taught by Zuk et al..

Art Unit: 1641

Conclusion

14. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JACOB CHEU whose telephone number is (571)272-0814. The examiner can normally be reached on 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jacob Cheu/
Examiner, Art Unit 1641